OCT 3 0 2003

RICHARD WOLF
Medical Instruments Corporation

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K030082

13.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **January 8, 2003**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: Power Control 2303 with Power Stick M4		Model number: 2303.011/ .901/ .911, 8564.121/ .851	
Common name: Motor control, motor handle		Classification name: Electric surgical rotary blade/ abrader	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K871250	1 Intra-articulated arthro power system 2161	1 Richard Wolf
2 K970088	2 RIWO DRIVE 2302 Generator and accessories	2 Richard Wolf
3 K984521	3 RIWO DRIVE small handle	3 Richard Wolf
4 K002328	4 SIOS-Interface for various devices	4 Richard Wolf

1.0 Description

The POWER CONTROL 2303 controls the motor in the POWER STICKS M3 and M4 that drives rotary blades and abraders, operated by a footswitch.

2.0 Intended Use

The Power Control 2303 in connection with Power Stick M4 (8564.121) or alternatively Power Stick M3 (8563.111/311) serves to drive Wolf rotary blades/ abraders and morcellators (tissue punches) for removal of tissue in endoscopic operations. At the same time aspiration allows continuous removal of ablated tissue.

For use with endoscopic accessories:

- In arthroscopy, e.g. for meniscus resection, removal of soft tissue as well as intraarticular severing or abrasion of osseous tissue (e.g. in ACL or shoulder operations)
- In thorax surgery, e.g. for removing hematomas
- In sinus surgery, e.g. for removing of polyps
- In spinal surgery (arthroscopic microdiskectomy (AMD)), e.g. for the removal of degenerated tissue

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3.0 Technological Characteristics

The POWER CONTROL 2303 is controlled by software.
The modes clockwise, counter-clockwise or oscillation can be selected in four speed ranges from 100 rpm up to 6000 rpm. The stop position of the rotary blade can be set and stored, so that the blade will always stop in this position until it is removed.

Values, functions and components are monitored at the graphically LCD display in various languages, accompanied by optical and acoustic signals.

Via the integrated CAN-BUS interface, the POWER CONTROL 2303 can be integrated into the R.Wolf RIWO NET SYSTEM with remote control, speech control and touch-screen monitor.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-devices sold by Richard Wolf.

5.0 Performance Data

The POWER CONTROL System 2303 was designed to meet the standards IEC601-1, IEC601-1-2 and UL2601-1.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa Date: August 20, 2003

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K030082
Trade/Device Name: Power Control 2303 with Power Stick M4
Regulation Number: 21 CFR 888.1100, 878.4820
Regulation Name: Arthroscope, Surgical instrument motors
Regulatory Class: II
Product Code: HRX, HWE, GEY
Dated: August 21, 2003
Received: August 22, 2003

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): K030082

Device Name: Power Control 2303 with Power Stick M4

Intended use: The Power Control 2303 in connection with Power Stick M4 (8564.121) or alternatively Power Stick M3 (8563.111/311) serves to drive Wolf rotary blades/ abraders and morcellators (tissue punches) for removal of tissue in endoscopic operations. At the same time aspiration allows continuous removal of ablated tissue.

Indication and Field of Use:

For use with endoscopic accessories:

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- In thorax surgery, e.g. for removing hematomas
- In sinus surgery, e.g. for removing of polyps
- In spinal surgery (arthroscopic microdiskectomy (AMD)), e.g. for the removal of degenerated tissue

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030082

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter _____
Per 21 CFR 801.109

(Optional Format 1'2-96)